CFA

Consumer Federation of America

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Performance Standard for Vibrio Vulnificus; Request for Comments
Docket No. 98P-0504
64 Fed.Reg. 3300 (January 21, 1999)

The following comments represent the views of the Consumer Federation of America, a non-profit association of more than 250 organizations, representing the interests of over 50 million Americans. CFA works to advance the consumer interest through advocacy and education.

For too many years, raw molluscan shellfish contaminated with the deadly bacterium *Vibrio vulnificus* have exacted a terrible toll on consumers in the United States. Since 1989, the pathogen has killed over 100 people and has sickened many more. The annual death toll has reached as high as 24 (in 1996), and last year another 18 victims died as a result of eating raw shellfish containing *Vibrio vulnificus*. And the pathogen did not take long to strike again this year: on February 3, a Florida man who had consumed raw oysters contaminated with *Vibrio vulnificus* was treated in an emergency room for fever, nausea, vomiting, diarrhea, and abdominal cramps. While this victim did not die as a result of his *Vibrio vulnificus* infection, there is every reason to expect that the pathogen will kill another 10 to 20 consumers before the end of the year, unless immediate, decisive action is taken to improve the safety of raw molluscan shellfish.

The surest way to end this unnecessary loss of life would be for FDA to transform its lax regulations into effective rules that actually prevent dangerously contaminated products from reaching restaurants and stores. We therefore support the

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CSPI petition urging FDA to take immediate regulatory action to establish a performance standard for raw molluscan shellfish from waters associated with past *Vibrio vulnificus* infections. The performance standard should require that shellfish processors reduce the pathogen to nondetectable levels in molluscan shellfish intended for raw consumption. With new post-harvest treatment technologies capable of reducing *Vibrio vulnificus* contamination in raw shellfish to nondetectable levels, FDA can act to protect consumers from unnecessary health risks by requiring that the industry produce a significantly safer product, without imposing inordinate costs on the industry.

A Growing Number of American Consumers are at Risk

The need for FDA to take such action is becoming ever more urgent, as the number of people who are especially vulnerable to *Vibrio vulnificus* continues to rise. In addition to those suffering from alcoholism, cancer, and AIDS, a large and growing segment of the population is included in the FDA's list of groups at high risk for serious complications from *Vibrio vulnificus*. For example:

- According to the American Liver Foundation, one out of every 20 Americans will be infected with hepatitis B in their lifetime, and 30 to 40 percent of people with acute hepatitis B show no symptoms.

- About four million Americans are infected with hepatitis C, and the FDA recently announced that an unknown number of Americans given blood transfusions before 1992 may have been exposed to the virus. Many people with hepatitis C also show few or no symptoms for many years.

- According to the American Diabetes Association, 16 million Americans have diabetes. Half of them -- eight million people -- don't know they have it.

- Approximately 30 percent of elderly Americans have low gastric acid.

Thus, with tens of millions of consumers affected, these conditions can no longer be said to be rare ailments in the U.S. population.

The Seafood HACCP Rule and Other Previous Regulatory Efforts Have Not Worked

Despite the mounting death and illness toll from *Vibrio vulnificus*-contaminated raw shellfish, and the growing number of potential victims, the regulatory response to this public-health disaster has been woefully inadequate. There is no evidence to suggest that the refrigeration controls, consumer education efforts, and warning label requirements adopted over the past few years by the harvesting states, in conjunction with the Interstate Shellfish Sanitation Conference (ISSC), have done anything to reduce the death and illness toll from contaminated shellfish. Indeed, careful scrutiny of these feeble measures reveals that even 100 percent compliance would do little to enhance shellfish safety:

- the already weak refrigeration requirements were further eviscerated at last year's ISSC annual meeting, to the point that they now permit raw shellfish routinely to remain unrefrigerated for up to 10 hours during the summer months, a sufficient period of time for *Vibrio vulnificus* concentrations to reach dangerous levels;

- research shows that consumer education in the form of warning signs in retail establishments are wholly inadequate to prevent at-risk individuals from eating raw shellfish; and

- the warning label requirement adopted by the ISSC does not even ensure that the warning will reach consumers, but instead requires warning labels to be affixed to bags of shellfish in wholesale shipments *to retailers*.

Even more disturbing than the states and the ISSC's failure to take appropriate action to protect consumers from shellfish contaminated with *Vibrio vulnificus* is FDA's inability to do so under the recently implemented seafood HACCP rule. In touting the expected economic benefits of that rule, FDA predicted that it would avert anywhere from 12 to 30 annual cases of *Vibrio vulnificus* infection within three years.

Unfortunately, there has been no decrease in the pathogen's annual death and illness toll since the rule was implemented in December 1997, and there is no reason to believe that the rule, without a mandatory performance standard, will bring any future improvement. Indeed, as CSPI pointed out in its citizen petition, even the head of FDA's Office of Seafood has conceded that the HACCP regulation alone will probably not bring about the estimated reduction in deaths and illnesses in the anticipated time frame.

Seafood HACCP's inability to stem the tide of *Vibrio vulnificus*-related deaths and illnesses is readily explained. In its current form, the rule mandates only ineffective pathogen-control measures for *Vibrio vulnificus*. Under the rule, harvesters and processors must comply with the weak refrigeration controls described above. The only additional pathogen-control measure is a tagging requirement, which mandates that shellfish be tagged with the location of harvest. While tagging does help to prevent processors from purchasing shellfish from harvesting beds that are closed due to sewage or other contamination, this device obviously fails to prevent processors from purchasing legally-harvested contaminated shellfish from beds that remain open despite the presence of high *Vibrio vulnificus* concentrations.

Despite these shortcomings, FDA could transform the seafood HACCP rule into an effective food-safety program for raw shellfish by combining the rule with a pathogen-reduction performance standard, as urged by CSPI. This would provide an incentive for the industry to employ available post-harvest treatments. Such a strategy has been successful in the meat and poultry industry, where the *Salmonella* performance standard imposed by the United States Department of Agriculture in conjunction with the meat and poultry HACCP program has apparently yielded an impressive decrease in *Salmonella* contamination of chicken, beef, and swine carcasses. There is every reason to believe that FDA could achieve similar success in eliminating *Vibrio vulnificus* from raw shellfish by adopting a performance standard as part of the overall seafood HACCP program. To avoid a loss in consumer confidence in seafood HACCP, which could undermine future efforts by FDA to implement HACCP programs in other areas of food regulation, FDA should act quickly to adopt the proposed performance standard.

The Performance Standard Must Require Nondetectable Levels of *Vibrio vulnificus*

To adequately protect consumers of raw shellfish, the performance standard must require nondetectable levels of the pathogen, and not some greater concentration. The infectious dose for *Vibrio vulnificus* is not known, but there is evidence that exposure to even very low levels of the pathogen can lead to death or serious illness. For instance, at least one person has died after eating a single contaminated raw oyster, and data from 1994 indicate that oysters containing under 300 *Vibrio vulnificus* organisms per gram of oyster meat at harvest can be deadly. Consequently, no scientific basis exists for setting a performance standard above nondetectability, and FDA would be acting arbitrarily -- and recklessly -- in establishing a standard that would permit raw shellfish containing any detectable *Vibrio vulnificus* organisms to leave processing plants.

Another consideration favoring adoption of a performance standard requiring nondetectable levels of *Vibrio vulnificus* is the likelihood that post-processing temperature abuse of raw shellfish would increase the pathogen's concentration to dangerous levels by the time the shellfish reach consumers. The organism's ability to proliferate rapidly even at room temperature means that raw shellfish containing low concentrations of *Vibrio vulnificus* could ultimately pose a grave risk to consumers, especially those in the high-risk groups.

The Potential Benefits of the Proposed Performance Standard Outweigh Its Potential Costs

Finally, it bears emphasis that adoption of the proposed performance standard would make sound economic sense. FDA has estimated the annual cost of *Vibrio vulnificus*-related deaths and illnesses at approximately $120 million. The annual cost is high in part because survivors of *Vibrio vulnificus* infection can face debilitating injury, sometimes requiring amputation and long-term rehabilitation.

This immense cost, imposed on society by an industry that, by recent estimates, has a gross income of only $36 million annually, would be eliminated by requiring the

industry to achieve nondetectable levels of the pathogen in their products. Of course, along with the quantifiable costs, the psychological costs of *Vibrio vulnificus*-related deaths and illnesses would also be eliminated or reduced by adoption of the proposed performance standard.

These annual savings would come at a modest price: according to a company that developed one post-harvest treatment process, mild heat pasteurization, the increase in cost would be approximately 8 cents per oyster. Moreover, the slight increase in cost per fish associated with implementation of the necessary post-harvest treatments could readily be passed on to consumers, who would be willing to pay more for a significantly safer product. Also as a consequence of the enhanced shellfish safety, demand for the treated products should increase, as more consumers become willing to eat raw shellfish.

Conclusion

Now is the time for FDA to act responsibly and stop the needless loss of life and serious illness caused by raw shellfish contaminated with *Vibrio vulnificus*. With the recent introduction of FDA's seafood HACCP rule and the development of innovative post-harvest processes that can reduce the pathogen to non-detectable levels, the agency is ideally positioned to put an end to the shellfish industry's unyielding reliance on traditional practices that allow potentially deadly products to reach consumers. By adopting the performance standard urged by CSPI, FDA finally can fulfill its public-health mission in this crucial area of seafood safety.

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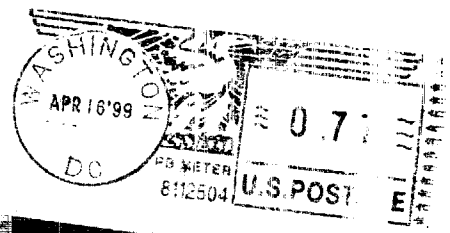

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